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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,936	12/22/1998	Scott Miller	BAYER 6 P1	8682

7590 05/03/2005

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EXAMINER

KUMAR, SHAILENDRA

ART UNIT PAPER NUMBER

1621

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/776,936

Applicant(s)

MILLER ET AL

Examiner

SHAILENDRA -. KUMAR

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 and 14 is/are allowed.
- 6) ☒ Claim(s) 1,3-11,13 and 15-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/10/05.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicants' communication filed on 2/10/05.

Claims 1 and 3-34 are pending in this application. Claim 2 has been canceled.

Claim Rejections - 35 USC § 112

1. Claims 15-19 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for the reasons as set forth in the office action of 11/2/04. Likewise, newly added claims 28-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for the reasons as set forth in the office action of 11/2/04. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' arguments were fully convinced and were not found convincing. Applicants argue that treatment of cancerous cells growth mediated by raf kinase i.e. to treatments that are not objectively doubtable. The examiner disagrees. This may be true for the research purposes only. But this not true for the actual treatment. Had it be true for the actual treatment, cancer would not have been the leading cause of the deaths. Applicants have merely discussed the theoretical aspects of the cancer in the first two pages of the instant specification, without substantiating with respect to their compounds, which are structurally so different to the literature they have cited. It is well known that many times in vitro studies can hardly be extrapolated to the in vivo studies. Applicants have even failed to provide any in vitro studies, leave alone, the in vivo

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studies. Applicants on page 21 of their response allege that Lemoine et al suggests that pancreatic cancer, acute myeloid leukemia, colorectal cancer, thyroid cancer, and non-small-cell lung carcinoma are associated with ras/raf kinase pathway. The examiner does not dispute that indeed Lemoin et al is an overview article, but with respect to the patentability of the instant claimed method, there is no relationship found in the instant specification.

Applicants allege that on page 74 of the instant specification they have provided data for 144 compounds. What applicants have provided is simply the IC50 data, and examiner would like to point out as to how these data are related to the treatment of various cancers as claimed herein. From the reference cited by the examiner, it can be at most concluded that the instant claimed compounds can be used for treating chemokine mediated diseases, absent evidence to the contrary.

Claim Rejections - 35 USC § 103

2. Claims 1, 3-11, 13 and 20-27 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Widdowson(WO'157), all for the reasons of record. Likewise, newly added claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Widdowson(WO'157), for the same reasons as applied to above claims in the office action of 11/2/04.

Applicants' arguments were fully considered and were not found convincing. Applicants admit that a small overlap exists between the substituents defined for L1 herein and the functional groups defined for R in the reference, however, applicants further allege that no claims as amended, are distinct from those of Widdowson since

the hydroxy substituted group ML1 is not at the ortho position of the phenyl ring.

Applicants further allege that there is no motivation to make positional isomer. The examiner disagrees. There is motivation to make positional isomers, because the positional isomers are prima facie obvious as a whole, absent evidence to the contrary.

In re Mehta, 146 USPQ 284. Applicants' arguments that In re Mehta is not a valid citation herein is not convincing. In herein also, there is only substituent which is positionally different, and one of ordinary skill in the art would have made positional isomer, with reasonable expectation of achieving a successful pharmaceutical composition, for treating chemokine mediated diseases, absent evidence to the contrary.

3. Claims 12 and 14 are free of prior art and are allowable.

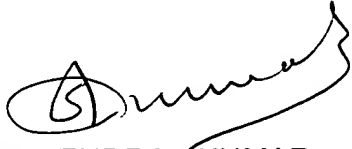
4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA - KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-83--.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAILENDRA - KUMAR
Primary Examiner
Art Unit 1621

S.Kumar
4/29/05